



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1271

[Docket No. FDA-2015-D-3719]

Draft Guidances Relating to the Regulation of Human Cells, Tissues, or Cellular or Tissue-Based Products; Public Hearing; Request for Comments; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public hearing; request for comments; correction.

SUMMARY: The Food and Drug Administration (FDA or Agency) is correcting a notification of a public hearing entitled “Draft Guidances Relating to the Regulation of Human Cells, Tissues, or Cellular or Tissue-Based Products; Public Hearing; Request for Comments” that appeared in the Federal Register of October 30, 2015 (80 FR 66845). The document announced a public hearing to obtain input on four recently issued draft guidances relating to the regulation of human cells, tissues, or cellular or tissue-based products (HCT/Ps). The document published with conflicting information about who must register for the public hearing. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Lori Jo Churchyard, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993, 240-402-7911.

SUPPLEMENTARY INFORMATION: In FR Doc. 2015-27703, appearing on pages 66845 and 66847 in the Federal Register of Friday, October 30, 2015, the following corrections are made:

1. On page 66845, in the third column under DATES, the third sentence is revised to read: "Persons seeking to attend (including FDA employees) or to present at the public hearing must register by January 8, 2016."

2. On page 66847, in the first column under section IV. Attendance and Registration, the third sentence is revised to read: "Individuals who wish to attend (including FDA employees) or present at the public hearing must register by sending an email to CBERPublicEvents@fda.hhs.gov on or before January 8, 2016, and provide complete contact information, including name, title, affiliation, address, email, and phone number."

Dated: December 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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